United States of America
FEDERAL TRADE COMMISSION
Washington, DC 20580

Division of Advertising Practices
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VIA ECF
Hon. Louis L. Stanton, U.S.D.J.
United States District Court
Southern District of New York
500 Pearl Street
New York, NY 10007

RE: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.* (17-CV-00124-LLS)
Pre-Motion Conference on Plaintiffs' Motion to Compel Answers of Deponent

Dear Judge Stanton:

Defendants' opposition to Plaintiffs' letter-motion, in addition to setting forth flawed legal arguments, makes clear that an outside party conducted an undisclosed study on apoaequorin on behalf of Defendants, with Defendants' knowledge and assistance. Should Defendants prevail in their arguments that Plaintiffs are not entitled to discover purely factual information about this study, Plaintiffs and this Court would be unable to assess a critical piece of evidence going to the core issues in this case – Prevagen's efficacy and Defendants' knowledge of the veracity of their advertising claims. Defendants' position, in addition to being legally flawed, is contrary to the long-held principle that parties "have a right to 'every man's evidence,' *United States v. Bryan*, 339 U.S. 323, 331, 70 S.Ct. 724, 730, 94 L.Ed. 884 (1950), and that wide access to relevant facts serves the integrity and fairness of the judicial process by promoting the search for the truth." *Shoen v. Shoen*, 5 F.3d 1289, 1292 (9th Cir. 1993). For the reasons set forth in Plaintiffs' initial letter-motion and below, the Court should grant Plaintiffs' request for pre-motion conference regarding a motion to compel testimony about this undisclosed study, as well as the 2016 re-write of the Madison Memory Study ("MMS").[1]

Defendants' opposition focuses almost exclusively on the argument that Plaintiffs cannot establish the exceptional circumstances necessary to discover information held by their consulting expert. As an initial matter, however, Defendants have failed to show that the study done by their expert after the MMS would not have been done in the ordinary course of business and is therefore entitled to protection. Given Defendants' record of conducting clinical trials absent the threat of litigation, as well as their statements following the MMS regarding additional studies on the purported target market for Prevagen, the declaration Defendants submitted is insufficient to establish that the post-MMS study was done "because of" anticipated litigation and is entitled to protection as work product. Furthermore, even if the Court finds that the study

[1] The same disputes arose in the August 20-21 30(b)(6) and individual depositions of Defendant Mark Underwood and Plaintiffs therefore incorporate a request to compel his testimony into the instant letter-motion.

is entitled to protection under Fed. R. Civ. Pro. 24(b)(4)(D), Plaintiffs can establish the requisite exceptional circumstances to obtain discovery of it.

The work product doctrine applies only to documents created "because of" the prospect of litigation. *United States v. Adlman*, 134 F.3d 1194, 1202 (2d Cir. 1998). "Accordingly … the work product doctrine does not extend to documents in an attorney's possession that were prepared by a third party in the ordinary course of business and would have been created in essentially similar form irrespective of any litigation anticipated by counsel." *Proctor & Gamble Co. v. Ultreo, Inc.*, 574 F.Supp.2d 334, 336-37 (S.D.N.Y. 2008) (quotation omitted). The burden is on the party claiming work product protection to prove that the document in question "would not have been prepared in substantially similar form but for the prospect of … litigation." *Id.* at 574 F.Supp.2d at 337 (quotation omitted). In *P&G*, a false advertising case, the court rejected the defendant's claims that five studies the company and its research affiliates had conducted were work product, despite the fact that the defendant's in-house attorney had submitted an affidavit stating he had advised the company to conduct the studies because of the prospect of litigation with the plaintiff. *Id.* at 335-38. The court found that, given the evidence that clinical and laboratory studies had long been part of the defendant's business plan, the defendant had failed to show the studies would not have been performed in substantially similar form but for the prospect of litigation. *Id.* at 337-38. Defendants in this case similarly have a record of conducting multiple human clinical studies, long predating any anticipated litigation, to substantiate their marketing claims, and in fact have conducted at least six human studies on Prevagen from 2008 to 2016. To substantiate the claim that Prevagen improves memory, they conducted the MMS from 2009 to 2011, which failed to find any benefit for the study populations as a whole. The write-ups of the MMS, including one from 2014, indicated that Plaintiffs intended to conduct further research to determine whether Prevagen might benefit a more targeted population with minimal or no cognitive impairment. In light of the failed MMS study, such research was necessary to meet the company's legal obligation to substantiate its ongoing claims. Defendants have failed to show they would not have performed the undisclosed post-MMS but for the anticipated litigation.[2]

Should the Court hold that Plaintiffs' questions implicate the work product protection as it applies to consulting experts, Plaintiffs can establish the exceptional circumstances necessary to discover such information. Courts have recognized the existence of exceptional circumstances where replicating expert discovery "would be judicially prohibitive." *Bank Brussells Lambert v. Chase Manhattan Bank*, 175 F.R.D. 34, 44 (S.D.N.Y. 1997); *see also In re "Agent Orange" Prod. Liabil. Litig.*, 105 F.R.D. 577, 580-81 (E.D.N.Y. 1985) (discovery allowed where duplicating experts' efforts would require such enormous time and resources that obtaining information by other means was impracticable). It would be prohibitively expensive for government enforcement agencies to test every advertised product to determine the legality of a

[2] Plaintiffs submit that, at a minimum, Defendants should submit the undisclosed study to the Court for *in camera* review to allow the Court to assess whether the face of the document indicates that it was created "because of" the prospect of litigation. *See Proctor & Gamble*, 574 F.Supp.2d at 338 (*in camera* review supported conclusion that studies were performed as routine business efforts to achieve substantiation for advertising claims).

seller's claims. Accordingly, the law places the burden on the marketer to have substantiation for its claims at the time it makes those claims. *See F.T.C. v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006) ("Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that Defendants' purported substantiation is inadequate, and the FTC need not conduct or present clinical studies showing that the product does not work as claimed."), *amended on reconsideration in part*, 472 F. Supp. 2d 990 (N.D. Ill. 2007), *aff'd*, 512 F.3d 858 (7th Cir. 2008); *In re People v. Applied Card Sys., Inc.*, 27 A.D.3d 104, 105 (3d Dep't 2005), *aff'd on other grounds*, 11 N.Y.3d 105 (2008) (noting that FTC Act case law is useful in interpreting New York Executive Law § 63(12) and the consumer protection provisions of the New York General Business Law). It would contravene public policy underlying consumer protection law to require Plaintiffs to conduct scientific research that Defendants should have conducted themselves to substantiate their claims. In this case, it appears Defendants have conducted such a study on Prevagen's efficacy, but are unwilling to disclose even the fact of its existence, let alone the scientific results – results that may go to the very heart of Defendant Underwood's knowledge of deceptive claims and his individual liability. *See F.T.C. v. Moses*, 913 F.3d 297, 306 (2d Cir. 2019); *People v. Apple Health & Sports Clubs*, 80 N.Y.2d 803, 807 (1992). At a minimum, Plaintiffs are entitled to discover the basic fact of whether the study exists and to have access to the data.

Finally, Defendants undoubtedly have waived any protection that might once have existed with regard to the 2016 re-write of the MMS. Parties waive protection, including that afforded consulting experts, by using protected materials in a manner inconsistent with the principles underlying privilege. *See, e.g.*, *Granite Partners, L.P. v. Bear, Stearns & Co.*, 184 F.R.D. 49, 54 (S.D.N.Y. 1999); *Agron v. Trustees of Columbia Univ.*, 176 F.R.D. 445, 449 (S.D.N.Y. 1997). Furthermore, subject matter waiver is appropriate where a party has used privileged material to benefit its strategic position in litigation. *See Favors v. Cuomo*, 285 F.R.D. 187, 198-200 (S.D.N.Y. 2012); *City of Capitola v. Lexington Ins. Co.*, No. 12-3428 LHK (PSG), 2013 WL 1087491, at *1-2 (N.D. Cal. Mar. 13, 2013). Defendants have waived all protection for the 2016 re-write—and all documents related to the same subject matter—by (1) producing it to Plaintiffs; (2) posting it on their website; and (3) relying on it in their motion to dismiss Plaintiffs' case. Defendants' objections to even basic questions regarding the re-write after using it in such fashion are completely meritless.[3]

For the above reasons, Plaintiffs ask the Court to grant their request for a pre-motion conference.

Respectfully,

/s/ Edward Glennon
Edward Glennon, Attorney
Federal Trade Commission

[3] As Plaintiffs noted in their initial letter-motion, a discovery dispute involving the FTC's subpoena of Georgetown Economic Services, Inc., originally filed in the D.D.C., has been transferred to this Court. *FTC v. Quincy Biosciences Holding Co.*, No. 1:20-mc-00307-LLS. The FTC's briefs in that matter are attached as Exhibits A (motion) and B (reply).